

The Breathe Right Company

February 23, 2005

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Food & Drug Administration Center for Food Safety and Applied Nutrition Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810) 5100 Paint Branch Parkway College Park, MD 20740

Subject:

Notification of Structure/Function Claims, Dietary Supplement

CNS, Inc., Minneapolis, MN 55439

FiberChoice® chewable tablets and FiberChoice® drops

This letter shall serve as a notification for the use of structure/function claims in the labeling and advertising of a dietary supplement in accordance with 21 CFR 101.93. CNS, Inc. uses the structure/function claims on the following page with the dietary supplements FiberChoice® chewable tablets and FiberChoice® drops. The dietary ingredient of interest is fiber in the form of inulin. Both products contain four grams of inulin in a dose.

These claims will be accompanied by the following disclaimer upon the next printing of labels and labeling material.

"These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

This information is complete and accurate. CNS has substantiation that these statements are truthful and not misleading. If you have any questions, please feel free to contact me at the numbers provided below.

Sincerely.

Gus Fenton

Director of Quality Assurance and Product Development

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CNS, Inc.
Minneapolis, MN 55439
FiberChoice® chewable tablets and FiberChoice® drops
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## Structure/Function Claims to be made on product label and labeling material

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"Inulin helps boost calcium absorption*."
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(Note: the claims above would be footnoted to the statement below)

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<sup>&</sup>quot;Inulin found in FiberChoice helps boost calcium absorption\*."

<sup>&</sup>quot;Soluble fiber found in FiberChoice helps boost calcium absorption\*."

<sup>&</sup>quot;FiberChoice helps boost calcium absorption\*."

<sup>&</sup>quot;Inulin helps your body absorb calcium\*."

<sup>&</sup>quot;Inulin found in FiberChoice helps your body absorb calcium\*."

<sup>&</sup>quot;Soluble fiber found in FiberChoice helps your body absorb calcium\*."

<sup>&</sup>quot;FiberChoice helps your body absorb calcium\*."

<sup>&</sup>quot;\*Studies have shown that 8g per day of inulin (a natural dietary fiber) increases calcium absorption. Each serving of FiberChoice® contains 4g of inulin."

<sup>&</sup>quot;Fiber is important to your overall health."

<sup>&</sup>quot;Dietary fiber, like that found in FiberChoice, is important to your overall health."

<sup>&</sup>quot;Soluble fiber found in FiberChoice is important to your overall health."

<sup>&</sup>quot;Fiber can be an important part of your overall good health."

<sup>&</sup>quot;Dietary fiber, like that found in FiberChoice, can be an important part of your overall good health."

<sup>&</sup>quot;Soluble fiber found in FiberChoice can be an important part of your overall good health."

<sup>&</sup>quot;FiberChoice can be an important part of your overall good health."

<sup>&</sup>quot;FiberChoice promotes good digestive health and regularity."

<sup>&</sup>quot;FiberChoice promotes good digestive health."

<sup>&</sup>quot;FiberChoice promotes regularity."

<sup>&</sup>quot;FiberChoice is a natural aid to good digestive health and regularity."

<sup>&</sup>quot;FiberChoice is a natural aid to good digestive health."

<sup>&</sup>quot;FiberChoice is a natural aid to regularity."

- "FiberChoice helps maintain good digestive health and regularity."
- "FiberChoice helps maintain good digestive health."
- "FiberChoice helps maintain regularity."
- "Fiber supports colon health."
- "Dietary fiber found in FiberChoice supports colon health."
- "Soluble fiber found in FiberChoice supports colon health."
- "FiberChoice supports colon health."
- "Inulin helps promote better digestion."
- "Inulin found in FiberChoice helps promote better digestion."
- "Soluble fiber found in FiberChoice helps promote better digestion."
- "FiberChoice helps promote better digestion."
- "Inulin promotes a healthy digestive system."
- "Inulin found in FiberChoice promotes a healthy digestive system."
- "Soluble fiber found in FiberChoice promotes a healthy digestive system."
- "FiberChoice promotes a healthy digestive system."
- "Inulin assists in restoring and maintaining intestinal flora."
- "Inulin found in FiberChoice assists in restoring and maintaining intestinal flora."
- "Soluble fiber found in FiberChoice assists in restoring and maintaining intestinal flora."
- "FiberChoice assists in restoring and maintaining intestinal flora."
- "Inulin is a prebiotic which helps grow beneficial bacteria for good digestive balance."
- "Inulin found in FiberChoice is a prebiotic which helps grow beneficial bacteria for good digestive balance."
- "FiberChoice contains a prebiotic (inulin) which helps grow beneficial bacteria for good digestive balance."
- "Inulin provides prebiotic nutrients that help grow the beneficial bacteria and prevent harmful bacteria."
- "Inulin found in FiberChoice provides prebiotic nutrients that help grow the beneficial bacteria and prevent harmful bacteria."
- "FiberChoice provides prebiotic nutrients that help grow the beneficial bacteria and prevent harmful bacteria."

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- "Inulin helps keep blood sugar levels more uniform."
- "Inulin found in FiberChoice helps keep blood sugar levels more uniform."
- "FiberChoice helps keep blood sugar levels more uniform."
- "Soluble fiber found in FiberChoice helps keep blood sugar levels more uniform."
- "Soluble fiber like that found in FiberChoice helps control weight by helping you feel full longer."
- "Inulin found in FiberChoice helps control weight by helping you feel full longer."
- "FiberChoice helps control weight by helping you feel full longer."
- "Soluble fiber found in FiberChoice helps control weight by helping you feel full longer."
- Soluble fiber like that found in FiberChoice helps control weight by helping you feel full longer and curb cravings."
- "Inulin found in FiberChoice helps control weight by helping you feel full longer and curb cravings."
- "FiberChoice helps control weight by helping you feel full longer and curb cravings."
- "Soluble fiber found in FiberChoice helps control weight by helping you feel full longer and curb cravings."
- "Soluble fiber like that found in FiberChoice helps maintain weight by helping you feel full longer."
- "Inulin found in FiberChoice helps maintain weight by helping you feel full longer."
- "FiberChoice helps maintain weight by helping you feel full longer."
- "Soluble fiber found in FiberChoice helps maintain weight by helping you feel full longer."
- Soluble fiber like that found in FiberChoice helps maintain weight by helping you feel full longer and curb cravings."
- "Inulin found in FiberChoice helps maintain weight by helping you feel full longer and curb cravings."
- "FiberChoice helps maintain weight by helping you feel full longer and curb cravings."
- "Soluble fiber found in FiberChoice helps maintain weight by helping you feel full longer and curb cravings."
- "Inulin helps enhance your immune system."
- "Inulin found in FiberChoice helps enhance your immune system."
- "FiberChoice helps enhance your immune system."
- "Soluble fiber found in FiberChoice helps enhance your immune system."

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"Inulin helps enhance your immune system to keep you healthy."

"Inulin found in FiberChoice helps enhance your immune system to keep you healthy."

"FiberChoice helps enhance your immune system to keep you healthy."

"Soluble fiber found in FiberChoice helps enhance your immune system to keep you healthy."

"Inulin supports beneficial intestinal bacteria that helps keep you healthy by enhancing your immune system."

"Inulin found in FiberChoice supports beneficial intestinal bacteria that helps keep you healthy by enhancing your immune system."

"Soluble fiber found in FiberChoice supports beneficial intestinal bacteria that helps keep you healthy by enhancing your immune system."

"Inulin supports beneficial intestinal bacteria that helps keep you healthy by stimulating your immune system."

"Inulin found in FiberChoice supports beneficial intestinal bacteria that helps keep you healthy by stimulating your immune system."

"Soluble fiber found in FiberChoice supports beneficial intestinal bacteria that helps keep you healthy by stimulating your immune system."

"Inulin helps strengthen your body's defense system."

"Inulin found in FiberChoice helps strengthen your body's defense system."

"FiberChoice helps strengthen your body's defense system."

"Soluble fiber found in FiberChoice helps strengthen your body's defense system."